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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/680,676 | 10/07/2003 | Mitchell R. Toland | WEYE121907/22822C | 5444 |

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EXAMINER

LANKFORD JR, LEON B

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/680,676

Applicant(s)

TOLAND, MITCHELL R.

Examiner

Leon Lankford *

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments filed 3/21/05 have been fully considered but they are not persuasive. The claims remain rejected for the reasons of record.

The claims remain rejected for the reasons of record under 35 *USC* § 112 first paragraph because it does not appear that the claimed invention was in possession of the inventor or that the instant invention enables the claimed invention. The declarations have been considered but the declarations fail to overcome the shortcomings of the instant specification in enabling or showing possession of the claimed invention. Applicant has demonstrated that embryos have different raw digital images but not that unknown embryos can be selected using a classification model and shown to exhibit the "characteristic" for which they are selected.

It also follows that applicant is intending to show possession and enablement for generic claims to "quantifiable characteristics" however the specification does not contain an adequate description for the entire scope of this phrase and thus the claims. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

Further, applicant argues that the instant method employs “more than embryo perimeter data” but the majority of the claims contain no such limitation. Applicant's arguments have been considered however a showing to overcome a prima facie case of obviousness must be clear and convincing(In re Lohr et al. 137 USPQ 548) as well as commensurate in scope with the claimed subject matter (In re Lindner 173 USPQ 356; In re Hyson, 172 USPQ 399 and In re Boesch et al., 205 USPQ 215 (CCPA 1980).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Further, the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims a method for classifying plant embryo's “quantifiable characteristics,” yet within the specification as originally filed, there is no clear

correlation drawn between the data collected and compared and the desired “quantifiable characteristics” of an embryo. Applicant has not clearly established what the correlation is and thus it is unclear that applicant actually had within their possession a method for actually classifying plant embryos.

Applicant theorizes that the raw digital image data analysis of embryo can be standardized such that a known desirable standard can be used to determine the ultimate characteristics of embryos by analyzing the raw digital image data produced thereby, however this has not been demonstrated. The specification explains how to obtain raw data however the specification does not describe the claimed invention. Applicant has not described the invention in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. There is no description of how the data can be effectively used. The invention has not been adequately described.

It follows logically that the claimed invention has not been enabled by the instant specification because applicant has not taught how to classify embryos wherein the “raw spectral data” of an embryo with desired “quantifiable characteristics” is used as a standard to which embryos of unknown quality are compared wherein if the data matches(?) then the unknown is classified as having desired quantifiable characteristics which would appear to be applicant’s invention. The specification shows no correlation between “raw digital image data” and the desired characteristics but only

between "raw digital image data" of one embryo and "raw digital image data" of a subsequent embryo.

It would appear that applicant is claiming that if an unknown embryo has the same "raw digital image data" as the reference embryo then it has the same desired quantifiable characteristics but applicant has not set forth how a different result is to be classified. Thus applicant has not described or enabled how to classify an embryo. What parameters or data would show that an embryo is of lesser desired quantifiable characteristics? Greater desired quantifiable characteristics? There appears to be no indication of how the reference and model are used to classify the embryos of a desired quantifiable characteristic(s).

There appears to be no adequate description for the specific qualities applicant claims in claims 14. The specification appears to be speculative in the ability to use spectral data to classify/select an embryo with any or all of the claimed properties.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the

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various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14 are rejected under 35 U.S.C. 103(a) as obvious over Chi et al (*J of Fermentation and Bioengineering* Vol81(5)) and/or Vits et al (*AIChE Journal* Vol40(10)).

Chi and Vits teach collecting visual and spectral data from somatic embryos to quantify the morphology and thus the stage of the embryos. The references teach visually or spectrally assessing the morphology of embryos and determining the stage of the embryo using algorithms. The claimed invention differs in that the methods of the references use different mathematic means. However the applicant uses known algorithms and programs to analyze the data and the use of such mathematic means would have been obvious to one of ordinary skill in the art at the time the invention was made given the guidance provided by Chi and Vits wherein the means used is a known statistical means for comparing similar types of data.

Accordingly, the claimed invention was at least prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

Conclusion

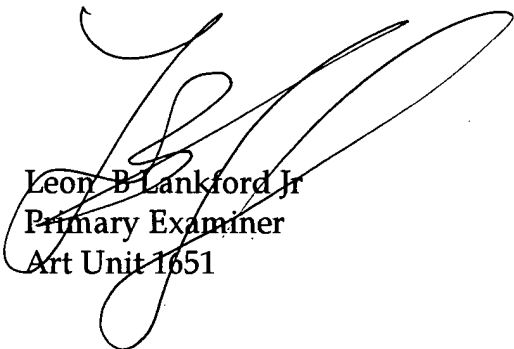
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Lankford whose telephone number is 571-272-0917. The examiner can normally be reached on Mon-Thu 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leon B. Lankford Jr.
Primary Examiner
Art Unit 1651